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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,698	06/02/2005	Magnus Von Knebel-Doeberitz	03528.0145.00US00	9319

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EXAMINER	
SHAW, AMANDA MARIE	

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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,698	VON KNEBEL-DOEBERITZ ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-2, 11, 17, and 30-31, drawn to nucleic acid sequences, pharmaceutical compositions comprising nucleic acids, and kits comprising nucleic acids.

Group 2, claim(s) 3-4, 11, 17, and 30-31, drawn to polypeptides, pharmaceutical compositions comprising polypeptides, and kits comprising polypeptides.

Group 3, claim(s) 5-10, drawn to a treatment method comprising administering a nucleic acid according to claim 1.

Group 4, claim(s) 5-10, drawn to a treatment method comprising administering a polypeptide according to claim 3.

Group 5, claim(s) 12 and 15-16, drawn to a method for detecting a disorder comprising detecting the presence of a nucleic acid.

Group 6, claim(s) 12 and 15-16, drawn to a method for detecting a disorder comprising detecting the presence of a polypeptide.

Group 7, claim(s) 13, drawn to a method for detecting a disorder comprising detecting the presence of antibodies directed against one or more polypeptides according to claim 3.

Group 8, claim(s) 14, drawn to a method for detecting a disorder comprising detecting the presence of a cell directed against one or more polypeptides according to claim 3.

Group 9, claim(s) 18-29, drawn to a treatment method comprising administering a set of at least 5 nucleic acids.

Group 10, claim(s) 18-29, drawn to a treatment method comprising administering a set of at least 5 polypeptides.

Group 11, claim(s) 32-42, drawn to a method for detecting a disorder comprising detecting the presence of antibodies directed against one or more polypeptides.

Group 12, claim(s) 32-42, drawn to a method for detecting a disorder comprising detecting the presence of a cell directed against one or more polypeptides.

2. The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the linking technical feature of a nucleic acids with frame shift mutations does not constitute a contribution over the prior art. For example, Mori et al (Cancer Research 2001) teach that the AIM2 gene is frequently mutated in the A10 repeat region which results in a frame shift mutation (Table 2). Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

3. In addition, each group encompasses multiple nucleic acids sequences, polypeptides, antibodies and cells.

The claims of Group 1, 3, 5, and 9 encompass a multitude of genes comprising frame shift mutations. In the instant case the description fails to disclose that all of the genes share a common property or activity. Moreover, since the nucleic acid sequences of these genes are not homologous to one another, they fail to share a common structure. Since neither of these two requirements is met, the group of genes claimed does not meet the requirement of unity of invention.

Therefore if Applicants elect group 1:

For claims 1-2 they must further elect a single gene according to claim 1.

For claim 11 they must further elect a single gene according to claim 1.

For claim 17 they must further elect a single combination of one or more genes according to claim 1.

For claims 30-31 they must further elect a single combination of at least 5 genes recited in claim 18.

Therefore if Applicants elect group 3:

For claims 5-10 they must further elect a single combination of one or more genes according to claim 1.

Therefore if Applicants elect group 5:

For claim 12 they must further elect a single combination of one or more genes according to claim 1.

Therefore if Applicants elect group 9:

For claims 18-29 they must further elect a single combination of at least five genes recited in claims 18-29.

The claims of Group 2, 4, 6, and 10 encompass a multitude of polypeptides. In the instant case the description fails to disclose that all of the polypeptides share a common property or activity. Moreover, since the amino acids encoding these polypeptides are not homologous to one another, they fail to share a common structure. Since neither of these two requirements is met, the group of polypeptides as claimed does not meet the requirement of unity of invention.

Therefore if Applicants elect group 2:

For claims 3-4 they must further elect a single polypeptide according to claim 3.

For claim 11 they must further elect a single polypeptide according to claim 3.

For claim 17 they must further elect a single combination of one or more polypeptides according to claim 3.

For claims 30-31 they must further elect a single combination of at least 5 polypeptides recited in claim 18.

Therefore if Applicants elect group 4:

For claims 5-10 they must further elect a single combination of one or more polypeptides according to claim 3.

Therefore if Applicants elect group 6:

For claim 12 they must further elect a single combination of one or more polypeptides according to claim 3.

Therefore if Applicants elect group 10:

For claims 18-29 they must further elect a single combination of at least five polypeptides recited in claims 18-29.

The claims of Group 7 and 11 encompass a multitude of antibodies. In the instant case the description fails to disclose that all of the antibodies share a common property or activity. Moreover, since the amino acids encoding these antibodies are not homologous to one another, they fail to share a common structure. Since neither of these two requirements is met, the group of antibodies claimed does not meet the requirement of unity of invention.

Therefore if Applicants elect group 7:

For claim 13 they must further elect antibodies directed against a single combination of one or more polypeptides according to claim 3.

Therefore if Applicants elect group 11:

For claims 32-42 they must further elect antibodies directed against a single combination of one or more polypeptides recited in claims 32-42.

The claims of Group 8 and 12 encompass a multitude of cells. In the instant case the description fails to disclose that all of the cells share a common property or activity.

Moreover, the cells fail to share a common structure. Since neither of these two requirements is met, the group of cells claimed does not meet the requirement of unity of invention.

Therefore if Applicants elect group 8:

For claim 14 they must further elect cells specifically directed against a single combination of one or more polypeptides according to claim 3.

Therefore if Applicants elect group 12:

For claims 32-42 they must further elect cells specifically directed against a single combination of one or more polypeptides recited in claims 32-42.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER